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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,051	01/29/2007	Chris Cindrich	P-6244/C	4876

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EXAMINER	
SCHMIDT, EMILY LOUISE	

ART UNIT	PAPER NUMBER
3767	

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11/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,051	CINDRICH ET AL.	
	Examiner	Art Unit	
	Emily Schmidt	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. It is not clear which portion is the covering portion and which portion is the shielding portion as used with the device with the door as described in paragraphs 318-322 and Fig. 39. Therefore, the covering portion must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 716 and 718 as in the amended specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

3. The amendment filed June 30, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: amended paragraph [0214] adds new matter regarding the reservoir port and needle port which were not described in the original disclosure.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 2 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Gross et al. (US 6,186,982 B1).

With regard to claim 2, Gross et al. teach a device for delivering a medicament into a body of a patient by injection into or through a skin surface of a patient, comprising: a housing having a bottom surface (Fig. 6 housing 63) adapted to contact a skin surface of a patient, a needle aperture on said bottom surface and a top surface; an injection needle adapted for penetration of said skin surface and for movement through said needle aperture (Fig. 6 see needle and aperture generally indicated at 51); a reservoir (Fig. 1 reservoir 12), disposed within said housing, said reservoir in fluid communication with said injection needle; and a safety member (Fig. 6 member 52) adapted for movement substantially perpendicular to said bottom surface of said housing, said safety member having a skin contacting portion disposed about said needle aperture and substantially covered with adhesive (Fig. 4 side 56 is covered with adhesive, Col. 11 lines 40-41), and at least one shield (Fig. 6 see the members generally indicated at 75) protruding from said skin contacting portion, said safety member having a first position wherein said shield of said safety member is initially disposed within said housing and said skin contacting portion is substantially co-planar with said bottom surface of said housing, and a second position wherein said shield of said safety member is at least partially withdrawn from

said housing and said safety member at least partially covers said injection needle (see transition form Fig. 5 to Fig. 6); wherein when said device is placed upon said skin surface of said patient, said skin contacting portion of said safety member is temporarily adhered to said skin surface and when said device is removed from said skin surface, said adhesion of said safety member to said skin surface is sufficient to move said safety member from said first position to said second position (Col. 11 line 65-Col. 12 line 5).

With regard to claim 5, see the pressurization system for pressurizing the reservoir in Fig. 1 (pressurizing chamber 14).

6. Claims 3 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Gross et al. (US 6,500,150 B1).

With regard to claim 3, Gross et al. teach a device for delivering a medicament into a body of a patient by injection into or through a skin surface of a patient, comprising: a housing having a bottom surface (Fig. 11 device 10), a needle aperture on said bottom surface, and a top surface (Fig. 1 see aperture through which needle extends and top surface); an injection needle adapted for penetration of said skin surface and for movement through said needle aperture (Fig. 11 needle 17); a reservoir, disposed within said housing, said reservoir in fluid communication with said injection needle (Fig. 1 barrel 12); and a safety member (Fig. 11 member 22) adapted for rotational movement along an arcuate path relative to said bottom surface of said housing, said safety member having a skin contacting portion disposed about said needle aperture and is substantially covered with adhesive (Col. 8 lines 5-6), and a pivot (Fig. 1 about hinge 23), said safety member having a first position wherein said safety member is secured against said bottom

surface and substantially co-planar with said the bottom surface of said housing (Fig. 12), and a second position wherein said safety member is released and rotated about said pivot and said safety member at least partially covers said injection needle (Fig. 13); wherein when said device is placed upon said skin surface of said patient, said skin contacting portion of said safety member is temporarily adhered to skin surface and when said device is removed from said skin surface, said adhesion of said safety member to said skin surface is sufficient to rotate said safety member about said pivot from said first position to said second position (Col. 10 lines 14-22).

With regard to claim 6, see Col. 8 lines 34-41.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al. (US 6,186,982 B1) in view of Gross et al. (US 6,500,150 B1).

With regard to claim 1, Gross et al. '982 teach a device for delivering a medicament into a body of a patient by injection into or through a skin surface of said patient, comprising: a housing having a bottom surface adapted to contact a skin surface of a patient (Fig. 6 indicated at 63), a needle aperture on said bottom surface, and a top surface (Fig. 6 needle 51 extends through aperture); an injection needle adapted for penetration of said skin surface and for movement through said needle aperture (Fig. 6 needle 51); a reservoir, disposed within said housing, said

reservoir in fluid communication with said injection needle (Fig. 5 reservoir 59); and a safety member (Fig. 6 member 52) adapted for movement away from said bottom surface of said housing, said safety member having a covering portion disposed about said needle aperture (Figs. 5 and 6 portion of 52 which overlaps aperture area), and at least one shield protruding from said covering portion (Fig. 6 generally indicated at 75), said safety member having a first position wherein said shield of said safety member is initially disposed within said housing and said covering portion is substantially co-planar with said bottom surface of said housing, and a second position wherein said shield of said safety the member is at least partially withdrawn from said housing and at least partially covers said injection needle (see transition Fig. 5 to Fig. 6); a spring element to bias said shield and covering portion of said safety member toward said second position (Figs. 10A-10D, Col. lines 19-47); said spring element is free to urge said safety member into said second position, whereby, as said device is removed from said skin surface, said shield of said safety member emerges from said housing and at least partially covers said injection needle (Col. 11 line 65-Col. 12 line 5). Gross et al. '982 does not disclose using a moveable door. However, Gross et al. '150 teach using a moveable door member 27 (Figs. 3 and 4) which prevents movement of a safety member and is released after the device is placed upon the skin (Col. 8 lines 16-32) to allow movement of the safety member. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a moveable door in the device of Gross et al. '982 as in Gross et al. '150 because it would prevent premature injection and controls the release of the safety member.

With regard to claim 4, see the pressurization system for pressurizing the reservoir in Fig. 1 (pressurizing chamber 14).

Response to Amendment

9. The amendments to the claims have been entered and overcome the previous objections and rejections under 35 U.S.C. 112

Response to Arguments

10. Applicant's arguments with respect to claims 1 and 3 have been considered but are moot in view of the new ground(s) of rejection.

11. Applicant's arguments filed June 30, 2009 have been fully considered but they are not persuasive. Regarding applicant's arguments with respect to claim 2, Applicant has argued that the device in Gross et al. does not disclose perpendicular movement. However, the claim recites "a safety *member adapted for movement substantially perpendicular* to said bottom surface" the Examiner finds the movement of the safety member in Gross et al. to be *substantially* perpendicular. Further, the Examiner notes that the safety member of Gross et al. moves in the same manner as the structure in Applicant's invention as in Figs. 39-40.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gross (US 5,814,020).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/
Examiner, Art Unit 3767

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767